REMARKS

I. Status of the claims

With entry of this amendment, claims 1, 2, 5-7, 9 and 11 are pending and under consideration. In this amendment, Applicants have cancelled without prejudice or disclaimer withdrawn claims 3, 4, 8, 10, and 12-35. Applicants reserve the right to pursue the cancelled subject matter in one or more divisional applications.

Claim 1 has been amended to recite that the composition comprises "gemifloxacin, gemifloxacin methanesulfonate, or gemifloxacin methanesulfonate sesquihydrate." Support for this amendment can be found in the specification at least on page 1, lines 19-29, particularly at lines 27-29, and on page 4, lines 30-32. This amendment adds no new matter.

II. Double Patenting Rejection

The Office rejects claims 1, 2, 5-7, 9, 11, and 24-26 under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-5 and 14-25 in U.S. Patent No. 6,803,376. Office Action, page 2.

Applicants traverse the rejection. To advance this case to allowance, however, Applicants submit the enclosed terminal disclaimer. Accordingly, Applicants request that the Office withdraw the rejection.

III. Rejection Under 35 U.S.C. § 112, ¶1

The Office rejects claims 1, 2, 5-7, 9, 11 and 24-26 under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the enablement requirement. Office

Action, page 3. According to the Office, the claims are inclusive of all gemifloxacin compounds and/or derivatives. *Id.* at 4. The Office asserts that undue experimentation would be required of the skilled artisan because allegedly it is unpredictable whether all gemifloxacin compounds and derivatives are effective in modulating metabolism of ciprofloxacin-resistant *Streptococcus pneumoniae* and the specification provides guidance only for gemifloxacin. *Id.* at 4-5. Applicants respectfully traverse.

As amended, claim 1 recites that the composition comprises "gemifloxacin, gemifloxacin methanesulfonate, or gemifloxacin methanesulfonate sesquihydrate." The breadth of the claims is limited to gemifloxacin and a particular salt and hydrate of that compound. The specification describes those compounds on page 1, lines 19-29. Applicants submit that no undue experimentation is associated with making the compositions used in the methods.

The practice of the claimed method also does not require undue experimentation. The state of the art and the level of skill in the art in the field of microbiology is high. Methods for determining the ability of an antimicrobial compounds to modulate the metabolism of a given strain of bacteria were routine in the art, thus there is no need to describe those assays in detail in the specification. Agar dilution, microdilution, E-test and disk diffusion assays are each described in the specification on pages 5-8 and 12-13, and the specification provides working examples using gemifloxacin in each of those assays to show that gemifloxacin modulates the metabolism of ciprofloxacin-resistant pneumococci. As stated in the specification on page 5, lines 21-22, "susceptibility to gemifloxacin can be reliably tested by agar and microdilution, E-test and disk diffusion."

In addition, although the specification use the generic term "pneumococci" when discussing the data for the 200 clinical isolates tested in the working examples, this term includes *Streptococcus pneumoniae*, and it is clear from the remainder of the specification and its numerous references to *Streptococcus pneumoniae* that the data are applicable to that particular species of *Streptococcus*.

It is the Office's position that it would require undue experimentation to show how the other gemifloxacin compounds and/or derivatives recited in claims 24-26 (i.e., gemifloxacin, gemifloxacin mesylate, or gemifloxacin mesylate sesquihydrate) are effective in modulating the metabolism of ciprofloxacin-resistant *Streptococcus pneumoniae*. *Id.* at 5. The Office contends that there are "[n]o examples showing the administration of other gemifloxacin compounds and/or derivatives as set forth in claims 24-26." *Id.*

According to the M.P.E.P., "the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention." M.P.E.P. § 2164.04 (citing *In re Wright*, 999 F.2d 1557, 1562, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993)). Claim 1 recites that the composition comprises gemifloxacin, gemifloxacin methanesulfonate, or gemifloxacin methanesulfonate sesquihydrate. The Office, however, has provided no evidence or sound reasoning why it would be unpredictable that compositions comprising a salt or hydrate of a compound would function the same way in the claimed methods as the free form of the compound. As discussed, the specification provides working examples with gemifloxacin. Because gemifloxacin has the same core structure as its salts and hydrates, Applicants

respectfully submit that the working examples using gemifloxacin enable the full scope of the claims. Accordingly, they request the Office to withdraw the rejection.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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